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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,898	03/01/2002	Alexander Olek	81658A	4523
23685 7590 06/09/2009 KRIEGSMAN & KRIEGSMAN 30 TURNPIKE ROAD, SUITE 9 SOUTHBOROUGH, MA 01772				
EXAMINER DEJONG, ERIC S				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
06/09/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/087,898

**Applicant(s)**

OLEK ET AL.

**Examiner**

ERIC S. DEJONG

**Art Unit**

1631

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 22, 27, 29, and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 22, 27, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED OFFICE ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/13/2009 has been entered.

Claims 1-11, 13-21, 23-26, 28, and 31-44 are canceled. Claims 12, 22, 27, 29, and 30 are pending and are currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Allowable Subject Matter***

The previous objection to claims 12, 22, 27, 29, and 30 as being dependent upon a rejected base claim is withdrawn in view of amendments made to the instant claims and the new grounds of rejection presented below under 35 USC 101.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 22, 27, 29, and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. Further, the recent decision in *Comiskey* (2009) confirmed the opinion set forth in *Bilski* of the prohibition pre-empting an abstract idea or mental process in a claim. The revised *Comiskey* decision further reiterated the precedent set forth in *Richman*, 563 F.2d 1026, 1030 (CCPA 1977) wherein the court held the application unpatentable because "if a claim [as a whole] is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory."

In the instant case, the claims are directed to a method of determining a biological effect and/or activity of at least one pharmaceutical composition. The recited process involves the steps of obtaining biological samples A and B, analyzing the level of cytosine methylation therein, selecting chosen sites that are differentially methylated, and concluding from a knowledge database a biological effect or activity. Said claims do not recite any step wherein an active physical transformation of a particular article takes place. Rather, the instant claims only require obtaining samples in a particular condition for analysis of their respective state of methylation. The analysis recited in the instant

claims does not require physical transformation of an article. Further, the selection and conclusion steps read only on an abstract series of mental processes. The ultimate conclusion wherein a conclusion is communicated via the internet or intranet is further treated as insignificant post-solution activity since the communication of a result does not impact the earlier steps wherein said result is determined.

Therefore, the examiner must determine if the instant claims have a tie to a particular machine or apparatus. In the instant case, the claims do not recite any tie to a machine other than the ultimate step of communicating a conclusion to a computer via an internet or intranet connect. However, as indicated above, the final step of communicating a result has been treated as an insignificant, post-solution activity step.

For these reasons, the instant claims are directed to non-statutory subject matter.

For the benefit of applicant, the instant rejection could be overcome by amendment to the instant claims so as to recite active sample preparation steps whereby the "obtaining" steps require exposure of a pharmaceutical sample and the transformation of said sample methylation state. Further, the instant rejection could be overcome by amendment wherein the "analysis", "selection" and "conclusion" steps expressly recite the use of a suitably programmed computer. Applicants are further cautioned against the introduction of new matter and are requested to cite support from the instant specification for all claim amendments.

***Claim Rejections – 35 USC §102***

The rejection of claims 1-3, 5-11, 13-21, 23-26, 28, and 31 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Laird et al. (P/N 6,331,393 B1) in light of Klippel et al. (P/N 3,558,768) is withdrawn in view of the cancellation of said claims.

***Claim Rejections - 35 USC § 103***

The rejection of claims claims 1-3, 5-11, 13-21, 23-26, 28, 31, 43, and 44 under 35 U.S.C. 103(a) as being unpatentable over Laird et al. (P/N 6,331,393 B1) in light of Klippel et al. (P/N 3,558,768) as applied to claims 1-3, 5-11, 13-21, 23-26, 28, and 31 above, and further in view of Lorincz et al. (Molecular and Cellular Biology (2000) pages 842-850) is withdrawn in view of the cancellation of said claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/  
Examiner, Art Unit 1631